

November 3, 2021

To: Vaccine Providers

RE: Pfizer COVID-19 Vaccine for Children Ages 5 - 11 Now Authorized and Recommended

On Friday, October 28, 2021, the Federal Drug Administration (FDA) authorized the Pfizer-BioNTech COVID-19 vaccine for administration to children 5 – 11 years of age under emergency use authorization. On Tuesday, November 2, the Centers for Disease Control and Prevention’s (CDC) Advisory Committee for Immunization Practice (ACIP) voted 14-0 to recommend “**The Pfizer-BioNTech COVID-19 vaccine (2 doses, 10µg, IM) for children 5-11 years of age in the U.S. population under the FDA’s Emergency Use Authorization.**” This authorization applies to all children ages 5-11, including those with underlying conditions and previous COVID infection. Please see the [interim clinical considerations presentation](#) with important details on implementation and administration language for this pediatric population as reviewed by the committee.

Upon reviewing the ACIP recommendations, the CDC Director, Rochelle Walensky, MD, MPH, endorsed the recommendation and issued the following statement. *“Together, with science leading the charge, we have taken another important step forward in our nation’s fight against the virus that causes COVID-19. We know millions of parents are eager to get their children vaccinated and with this decision, we now have recommended that about 28 million children receive a COVID-19 vaccine. As a mom, I encourage parents with questions to talk to their pediatrician, school nurse or local pharmacist to learn more about the vaccine and the importance of getting their children vaccinated.”*

The Kansas Department of Health and Environment (KDHE) is authorizing COVID-19 enrolled vaccine providers to begin using the above CDC recommendation for administration of Pfizer COVID-19 vaccine for all children ages 5 – 11.

Here are some key takeaways from the ACIP discussions.

Safety/Efficacy Summary: The committee was presented with safety and efficacy data from the CDC and Pfizer, including much of the same data presented at last week's VRBPAC committee meeting. In summary, the vaccine was found to be 90.7% effective against symptomatic COVID disease. Out of the ~3,000 children vaccinated with the Pfizer vaccine during clinical trials, there were no deaths, no case of myocarditis, no Bell’s palsy and no anaphylaxis. COVID-19 disease and MIS-C result in higher rates of myocarditis than myocarditis related to the COVID vaccine: There have been 0 deaths related to myocarditis from the COVID-19 vaccine in adolescents and adults, a statistic many voting members felt compelling when deciding their vote. Furthermore, systemic and local reactions were *less severe* in the 5-11 cohort compared to older children and adolescents. The committee felt that the safety and efficacy data were clear and that benefits overwhelmingly outweigh the risks of COVID disease (i.e. MIS-C, unknown effects of long-term COVID, etc.)

Final Discussion: Overall, the committee felt that this vaccine is necessary to reduce deaths and burden of disease, both biological and societal. During the presentation of the Evidence to Recommendation (EtR) framework, a CDC analysis estimated that we need to vaccinate only 10

children to prevent a single case of COVID-19 in children 5-11. The committee discussed and felt strongly that the possibility of reducing any and all cases of COVID-19 would increase the possibility for more social interactions and uninterrupted school, not to mention prevention of transmission of COVID-19 to vulnerable family members. Recommending this vaccine increases equitable access and boosts overall immunity levels in the United States. There was little to no dissent between voting members during the discussion.

Several public commenters felt that the vaccine risk of adverse events, including myocarditis was high and that the disease is mild in children. They implored ACIP to vote against a universal recommendation. Experts presenting to CDC felt that the benefit of the vaccine outweighed the risk. [These slides may be helpful to you to address these concerns by parents](#). The trial was small compared to the adult trial, ~ 3,000 children --- but there were no cases of myocarditis. The safety monitoring will continue and is robust.

Vaccine Delivery: Vaccine will be delivered by early next, with most being delivered this week, for all providers who have pre-ordered the Pfizer pediatric doses either for direct shipment (larger order of 300 or increments of 300) or through redistribution from KDHE for smaller orders). Additional doses may be ordered through the regular [weekly vaccine ordering survey](#).

Providers who have questions may contact the Kansas Immunization Program at kdhe.vaccine@ks.gov .